Bost Available Copy

IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.

10/518,811

Applicants

: GANTZ, ET AL.

Filed

: DECEMBER 22, 2004

Title

COCHLEAR IMPLANT ELECTRODE ARRAY

Art Unit

: 3762

Examiner

TO BE ASSIGNED

Atty Docket No.

COCH-0129-US1

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

The below-identified communication(s) is (are) submitted in the above-captioned application or proceeding:

 \times

Certified copy of Australian Provisional Application No. PS 3227

Respectfully submitted,

Michael G. Verga

Registration Number 39,410

JAGTIANI + GUTTAG Democracy Square Business Center 10363-A Democracy Lane Fairfax, Virginia 22030

(703) 591-2664

January 30, 2006



Patent Office Canberra

I, JANENE PEISKER, TEAM LEADER EXAMINATION SUPPORT AND SALES hereby certify that annexed is a true copy of the Provisional specification in connection with Application No. PS 3227 for a patent by COCHLEAR LIMITED as filed on 28 June 2002.

AVENT OFFIC

WITNESS my hand this Twenty-fourth day of December 2004

JANENE PEISKER

<u>TEAM LEADER EXAMINATION</u>

<u>SUPPORT AND SALES</u>

CERTIFIED COPY OF PRIORITY DOCUMENT



AUSTRALIA

Patents Act 1990

Cochlear Limited

PROVISIONAL SPECIFICATION

Invention Title:

Cochlear implant electrode array

The invention is described in the following statement:

(--

"Cochlear Implant Electrode Array"

Field of the Invention

The present invention relates to an implantable cochlear electrode assembly. A method of implanting such a device is also described.

Background of the Invention

In modern society, the occurrence of hearing loss is quite common, with approximately 5 to 10% of the population suffering from some degree of hearing impairment. This can be attributed to a number of causes, such as prolonged exposure to loud sounds, the result of disease or illness, or congenital problems.

15

10

Hearing loss is generally of two types, namely conductive and sensorineural. Conductive hearing loss occurs when the normal mechanical pathways for sound to reach the hair cells in the cochlea are impeded, for example, by damage to the ossicles. In such cases, the hearing loss may often be improved by the use of conventional hearing aids, which amplify the sound so that acoustic information reaches the cochlea and the hair cells. Such hearing aids utilise acoustic mechanical stimulation, whereby the sound is amplified according to a number of varying techniques, and delivered to the inner ear as mechanical energy. This may be through a column of air to the eardrum, or direct delivery to the ossicles of the middle ear.

Sensorineural hearing loss, however, is due to the absence or destruction of the hair cells in the cochlea which are needed to transduce acoustic signals into auditory nerve impulses. Individuals suffering from this type of hearing loss are unable to derive any benefit from conventional hearing aid systems, no matter how loud the acoustic stimulus is made, because their mechanisms for transducing sound energy into auditory nerve impulses have been damaged. In such cases, cochlear implants have been developed to provide the sensation of hearing to such individuals. In cochlear implants, electrical stimulation is provided via stimulating electrodes positioned as close

as possible to the nerve endings of the auditory nerve, essentially bypassing the role of the hair cells in a normally functioning cochlea. The application of a stimulation pattern to the nerve endings causes impulses to be sent to the brain via the auditory nerve, resulting in the brain perceiving the impulses as sound.

5

As has been alluded to above, the treatment of both of these types of hearing loss has been quite different, relying on two quite different principles to deliver sound signals to be perceived by the brain as sound. It has been found that it is relatively common in hearing impaired individuals to experience sensorineural hearing loss for sounds in the high frequency range, and yet still be able to discern sounds in the middle to low frequency range, through the use of a conventional hearing aid, or naturally. Traditionally, in the majority of such cases, the individual would only receive treatment to preserve and improve the hearing for the middle to low frequency sounds, most probably via a conventional hearing aid, and little would be done to attempt to restore the hearing loss for the high frequency sounds. Only if the individual lost the ability to perceive the middle to low frequency sounds would consideration then be given to restoring the hearing loss for the high frequency sounds, in this case a cochlear implant would be considered a possible solution.

20

30

US Patent No 6,231,604 introduces the concept of combining the two treatments, namely acoustic mechanical stimulation and electrical stimulation, for individuals with some degree of intact residual hearing. In this patent the preferred embodiment makes mention of acoustic mechanical stimulation being used for sounds representative of low to mid-range frequencies in the acoustic environment, with electrical stimulation being used for sounds representative of mid to high-range frequencies in the acoustic environment. Whilst this patent identifies the need to attempt to combine the two stimulation methods it fails to suggest how such a system can be achieved, and the mechanism for performing this task.

International patent application WO 00/69513 describes a number of embodiments of an electrode array that may be used to deliver electrical stimulation to the associated regions of the cochlear in order to supplement hearing of high frequency sounds. In this application a relatively short and thin electrode array is described being between 6-8mm in length and which is

inserted through a small slit in the round window membrane for stimulation of the basal end of the scala tympani duct of the cochlea. In order to maintain the hydrodynamic nature of the cochlea, the described electrode array is provided with flexible flaps at its proximal end to assist in sealing the round window membrane and also to maintain the array in a position that is remote from both walls of the cochlea

Experimental tests have shown that electrode arrays inserted to a depth as described by the above patent application will produce unnatural and sharp or high-pitched percepts in a recipient. Trials of such an array to a depth of 8 mm into the cochlea have indicated that recipients are not able to fuse the electrical stimulus with the auditory stimulus received. Therefore, the electrode array as described by the above referenced patent application will be unable to provide benefit to the recipient because of restriction in depth of insertion which is mandatory to preserve residual hearing. Further, the electrode array of the above referenced patent application will most likely cause damage to the basal membrane due to rotation or twisting of the array about its longitudinal axis. As the array relies upon flexible flaps for stabilisation and not the fixation of the head of the device, it is highly likely, due to the rounded shoulder of the device, that the array will not be stable within the cochlea, potentially causing damage to the sensitive structures therein.

The present invention therefore aims to ameliorate the problems associated with the prior art and provide an electrical stimulation device which is able to restore high frequency sound perception whilst allowing natural hearing mechanisms to be restored and maintained for perception of low to medium frequency sounds.

The present invention also aims to provide a stable and safe electrode array which is able to be inserted to a desired depth within the cochlea to provide useful percepts for the recipient which will not cause damage to the sensitive structures of the cochlea.

The present invention also aims to provide a device which can be used to provide electrical stimulation for high to medium frequency sounds and has the ability, should a deterioration in the ability to perceive medium to low

sounds occur, to be upgraded to a complete electrode array capable of providing electrical stimulation for all frequency sounds.

Any discussion of documents, acts, materials, devices, articles or the like which has been included in the present specification is solely for the purpose of providing a context for the present invention. It is not to be taken as an admission that any or all of these matters form part of the prior art base or were common general knowledge in the field relevant to the present invention as it existed before the priority date of each claim of this application.

10

25

Summary of the Invention

Throughout this specification the word "comprise", or variations such as "comprises" or "comprising", will be understood to imply the inclusion of a stated element, integer or step, or group of elements, integers or steps, but not the exclusion of any other element, integer or step, or group of elements, integers or steps.

The present invention preferably provides a relatively very thin and short electrode array that is insertable into the basal region of the cochlea and past the first turn thereof. The electrode array preferably has minimal impact on the hydrodynamic behaviour of the cochlea and allows the user to gain maximum benefit from any residual hearing that they may possess.

According to a first aspect, the present invention is an implantable electrode array insertable through a cochleostomy into at least the basal region of the cochlea, the array comprising:

an elongate carrier having a proximal end, a distal end, and a plurality of electrodes supported by the carrier at respective spaced locations thereon in a region between the proximal end and the distal end; and

a stabilising collar means extending outwardly from the elongate carrier at or adjacent a proximal end thereof, the stabilising collar means having an abutment surface adapted to abut a portion of the cochlea surface around the cochleostomy and at least substantially prevent movement of the carrier following completion of insertion of the array into the recipient's body.

In one embodiment of this aspect, the collar means can comprise a portion of the carrier having a diameter greater than that of the remainder of the carrier. The diameter of the collar means can be constant along its length. In another embodiment, the diameter of the collar means can vary along its length.

In one embodiment, the collar means can have a first portion in which the diameter of the collar means expands away from the proximal end of the collar means. In this embodiment, the diameter can expand frusto-conically.

The frusto-conical portion can comprise between about 30% and 50% of the length of the collar means. The collar means can further comprise a second portion distal the proximal end of the collar means, The second portion is preferably constant in diameter along its length. The second portion preferably comprises between about 70% and 50% of the length of the collar means.

15

In one embodiment, the distal end of the stabilising collar means provides the abutment surface. The abutment surface preferably extends outwardly from the carrier for a length. In a further embodiment, the abutment surface extends outwardly substantially at a right angle, more preferably at a right angle, to the longitudinal axis of the carrier. As such, the abutment preferably provides a corner in the outer surface of the carrier that is adapted to abut the cochlea surface in the region around the cochleostomy once the array has been inserted through the cochleostomy and into place within the cochlea. This abutment preferably at least substantially prevents subsequent lateral movement of the array relative to the cochleostomy.

The collar is preferably positioned at the proximal end of the carrier. In a further embodiment, the collar means can be formed integrally with the carrier member. For example, the collar means can be moulded about the carrier member. In another embodiment, the collar means can be fabricated separately and connected to the carrier member.

In another embodiment, the stabilising collar is made of a flexible material at least similar to that used to form the carrier. Where the carrier is fabricated from a silicone compound, the stabilising collar means is also

preferably fabricated from a silicone compound, including the same silicone compound or a different silicone compound.

In a further embodiment, the array can further comprise an anchoring means extending outwardly from the collar means. The anchoring means is preferably adapted to be anchored with body tissues and/or bone near the cochleostomy site. In one embodiment the anchoring means preferably extends outwardly at or adjacent the abutment surface of the collar means. In one embodiment, the anchoring means can be made of a mesh material, such as Dacron. Sutures can preferably be passed through the mesh material and into the tissue and/or bone to secure the mesh to the tissue and/or bone. In one embodiment, the anchoring means is adapted to be sutured to the promontory bone.

In one embodiment, the mesh material comprising the anchoring means is moulded into place within the collar means. The mesh is preferably moulded at or adjacent the distal end of the collar means. The mesh preferably extends for a diameter that is at least about twice the diameter of the collar means. Other diameters of the mesh can be envisaged.

20

15

According to a second aspect, the present invention is an implantable electrode array insertable through a cochleostomy into at least the basal region of the cochlea, the array comprising:

an elongate carrier having a proximal end, a distal end, and a plurality of electrodes supported by the carrier at respective spaced locations thereon in a region between the proximal end and the distal end; and

an anchoring means extending outwardly from the elongate carrier at or adjacent a proximal end thereof and adapted to be anchored to body tissues or bone surrounding the cochleostomy and at least substantially prevent movement of the carrier following completion of insertion of the array into the recipient's body.

In this aspect, the anchoring means can be made of a mesh material, such as Dacron. Sutures can preferably be passed through the mesh material and into the tissue and/or bone to secure the mesh to the tissue and/or bone.

In one embodiment of this aspect, the anchoring means is adapted to be sutured to the promontory bone.

In a further embodiment of this aspect, the mesh material comprising the 5 anchoring means is moulded into place within the body of the carrier. The mesh is preferably moulded at or adjacent a proximal end of the carrier. The mesh preferably extends for a diameter that is at least about three times the diameter of the carrier. Other diameters of the mesh can be envisaged.

In one embodiment of both of the above aspects, the carrier can adopt a first configuration selected to allow the array to be inserted into a recipient's cochlea and at least a second configuration wherein said electrode array is adapted to apply tissue stimulation. The carrier is preferably formed to preferentially adopt the second configuration or another configuration different to said first configuration.

In a further embodiment of both aspects, the elongate carrier preferably has a length of between 6-10mm, and is insertable to a depth that just extends beyond the first turn of the cochlea.

20

10

In a still further embodiment of both aspects, at least one of the electrodes has a surface that is at least adjacent an inner surface of the carrier. More preferably, each of the electrodes in the array have a surface that is adjacent the inner surface of the carrier. In a further embodiment, the surfaces 25 of the electrodes are aligned with the inner surface of the carrier. In another embodiment, the surfaces of the electrodes stand proud of the inner surface of the carrier. It is also envisaged that the electrode surface could also be recessed into the inner surface of the carrier. In yet another embodiment, one or more electrodes may also be positioned on the outer surface of the carrier 30 not facing the modiolus. Such electrodes could act as additional ground or reference electrodes.

In yet another embodiment of both aspects, an indicator means may also be incorporated in the collar of the elongate carrier to convey to the surgeon 35 the orientation of the electrodes on the array. It is envisaged that the indicator means could be any means capable of representing an orientation of the array

whereby the electrodes can be positioned as desired within the cochlea. In order to achieve this the indicator means is preferably provided on the part of the array which is adapted to be positioned external to the cochlea following implantation of the carrier.

5

According to a third aspect, the present invention is a method of inserting a cochlear electrode array into at least the basal end of the scala tympani duct of a cochlea, said cochlear electrode array having a collar means attached thereto at or adjacent a proximal end thereof, the method comprising the steps of:

- (i) forming an opening into the cochlea to allow access thereto;
- (ii) inserting a distal end of said electrode array into the scala tympani duct and advancing the array therein; and
- (iii) securing said collar means to the tissue surrounding said opening
 in the cochlea, wherein said collar seals said opening into the cochlea and is arranged so that the electrode array is stabilised within the cochlea.

In this aspect, the electrode array and collar means can have the features of the array and collar means as defined herein.

20

In a further embodiment of this aspect, the method can comprise an additional step prior to step (ii), in which a facia washer is fabricated and placed over said electrode array prior to its insertion into the cochlea.

25

According to a fourth aspect, the present invention is a method of inserting a cochlear electrode array into at least the basal end of the scala tympani duct of a cochlea, said cochlear electrode array having an anchoring means extending outwardly therefrom at or adjacent a proximal end thereof, the method comprising the steps of:

30

35

- (i) forming an opening into the cochlea to allow access thereto;
- (ii) inserting a distal end of said electrode array into the scala tympani duct and advancing the array therein; and
- (iii) suturing said anchoring means to the tissue and/or bone surrounding said opening in the cochlea so as to stabilise the array within the cochlea.

In this aspect, electrode array and anchoring means can have the features of the array and anchoring means as defined herein.

In both the third and fourth aspects, the step of forming an opening to the cochlea can be performed via a normal cochleostomy using either a "soft surgery" technique or by drilling with a laser.

In the third and fourth aspects, the electrode array is preferably formed with at least some degree of curvature and inserted into the cochlea in a straight configuration, using a straightening stylet. Following insertion to a depth of preferably about 10mm, the straightening stylet is preferably removed and the array is allowed to return to its curved configuration.

Following insertion, the electrode array would be positioned in a manner whereby the electrodes are able to apply stimulation to the appropriate regions of the cochlea that detect sounds having high frequencies. The remaining structure of the cochlea would remain intact and allow the recipient to continue to use their residual hearing capability to detect sounds associated with middle to low frequency ranges.

20

Brief Description of the Drawings

By way of example only, a preferred embodiment of the invention is now described with reference to the accompanying drawings, in which:

25

- Fig. 1 is a pictorial representation of a prior art cochlear implant system;
- Fig. 2a is a side view of an electrode array made in accordance with the present invention;

30

. .

- Fig. 2b is a medial side view of the electrode array of Fig. 2a;
- Fig. 3 is a simplified depiction of a cochlea representing issues associated with inserting shortened electrodes into the basal region of the cochlea;

Fig. 4 is a view of an electrode of the present invention in its relaxed state;

Fig. 5 is a further simplified depiction of a cochlea representing further issues associated with inserting shortened electrodes into the basal region of the cochlea; and

Fig. 6 shows an implantable device of a further embodiment of the present invention.

Preferred Mode of Carrying out the Invention

Before describing the features of the present invention, it is appropriate to briefly describe the construction of one type of known cochlear implant system with reference to Fig. 1.

Known cochlear implants typically consist of two main components, an external component including a speech processor 29, and an internal component including an implanted receiver and stimulator unit 22. The external component includes a microphone 27. The speech processor 29 is, in this illustration, constructed and arranged so that it can fit behind the outer ear 11. Alternative versions may be worn on the body. Attached to the speech processor 29 is a transmitter coil 24 that transmits electrical signals to the implanted unit 22 via a radio frequency (RF) link.

25

10

The implanted component includes a receiver coil 23 for receiving power and data from the transmitter coil 24. A cable 21 extends from the implanted receiver and stimulator unit 22 to the cochlea 12 and terminates in an electrode array 20. The signals thus received are applied by the array 20 to the basilar membrane 8 and the nerve cells within the cochlea 12 thereby stimulating the auditory nerve 9. The operation of such a device is described, for example, in US Patent No. 4532930.

One embodiment of a cochlear implant electrode array, according to the present invention, is depicted generally as 30 in Figures 2a and 2b. Figure 2a is the side view of the electrode array 30 and Figure 2b is a view of the medial

side of the electrode array 30. It can be considered that the medial side of the electrode array 30 is the side on which a plurality of spaced apart electrode contacts 32 are located.

As seen in Figures 2a and 2b, the electrode array 30 includes a plurality of spaced apart electrode contacts 32 on a flexible carrier 31. In a preferred embodiment, each of the electrode contacts 32 reside on the same side, the medial side 33, of the carrier 31. Each electrode contact 32 has at least one wire conductor 34 connected thereto. These wire conductors 34 are embedded within the flexible carrier 31 and exit through a proximal end of the carrier 31 within a flexible cable 21. As previously described the flexible cable 21, including the wire conductors 34, is connected to the implanted receiver and stimulator unit 22. The wires therefore provide the means for making electrical contact with each of the electrode contacts 32 from unit 22.

15

5

At the proximal end of the electrode array 30 is a collar 35. The collar 35 is larger in diameter than the carrier 31, and is made from a similar flexible material, such as silicone. The distal end of the collar 35 provides an abutment surface 37. Embedded within the collar 35 adjacent the surface 37 is an 20 anchoring mesh material 36. In the depicted embodiment, the mesh material 36 is Dacron.

The right angle of the abutment surface 37 of the collar 35 with the outer surface of the carrier provides a square shoulder that at least substantially 25 prevents the array 30 from twisting following insertion in the duct of a cochlea. The purpose of the mesh material 36 incorporated into and extending further outwardly that the collar 35 is to allow the face 41 of the mesh to be fixed and anchored to the promontory bone and integrated into the surrounding fibrous tissue. This collar 35 and anchoring mesh 36 combination overcomes the problems associated with movement of the short electrode over time, and prevents further penetration of the electrode array 30 into the cochlea.

The wire conductors 34 pass through the collar portion 35, exiting via the cable 21, which is connected to the collar portion 35 at its proximal end.

The electrode array 30 also includes an indicator means 38 incorporated into the collar portion 35 to assist the surgeon in determining the orientation of the electrodes 32, once inserted into the cochlea. As the portion of the array, shown generally as 39, is intended to be inserted into the cochlea with only the collar 36 and the collar portion 35 being external of the cochlear, it is important that the surgeon is provided with an indication as to the orientation of the surface of the array bearing the electrodes 32. In one embodiment, the indicator means could be a portion of Dacron mesh correctly positioned on the collar portion 35 via a fastening means such as glue, and covered with a clear silicone material, preferably the same material as that used to make the collar portion 35, to reform the tubular shape of the collar portion 35.

As shown in Figures 2a and 2b, the electrode contacts 32 are positioned on the medial side of the electrode array, i.e. positioned on the same side of the carrier 31. The array is preferably cylindrical and has a small diameter resulting in the volume of the array 30 being minimised. Preferably, the cross sectional area of the array is 0.2 x 0.4mm. In normal hearing, the oscillation of the basilar membrane is required and the amplitude of the sound is dependant on the damping of the membrane motion by the fluid within the cochlea. 20 Therefore, it is important that when an electrode array is inserted into the cochlea with the intention to preserve this natural capacity to detect sounds, as is the case with the present invention, the volume of the array must be minimised so that this damping will not be affected by the exclusion of the cochlea fluid. The electrode array 30 is of a smaller diameter than a conventional electrode array, and in the embodiment as shown, includes 6 electrodes 32. The length of the inserted portion of the array L, is preferably set to be between 6-10mm. In a preferred embodiment, the array 30 is constructed, such as by moulding, to have a slightly curved configuration when in its relaxed state, as is shown in Figure 4. A stylet (not shown for clarity) can be used to hold the array in a straight configuration for insertion. This is well known in the art and is discussed in detail in International Publication No WO 00/71063, the contents of which are incorporated herein by reference.

Figure 3 is a simplified view of a cochlea 12 showing issues associated with inserting short electrodes into the cochlea. It has been found experimentally that an electrode inserted to a depth that is between positions A

& B will produce unnatural and sharp high pitch percepts for a recipient. In trials by the present applicant of a 6-electrode array inserted to a depth of 8mm into the cochlea, it was found that recipients could not fuse the electrical stimulus with the auditory stimulus received. As a result, in such a device as described in International Publication No WO 00/69513, it is highly unlikely that such an electrode would provide benefit to the user. Therefore, in order to provide useful percepts to the recipient, the electrode array needs to be inserted beyond a depth of 6-8mm, however providing this additional depth is a challenge.

10

As described previously, for devices such as the present invention, it is essential that the hydrodynamic nature of the cochlea be preserved in order to preserve the recipient's residual hearing. In order to achieve this it is essential that the sensitive structures of the cochlea be maintained and that the array does not damage the walls of the cochlea to alter the motion of the cochlea fluid. If the array is to be inserted beyond position A depicted in Figure 3, and to the desired depth to provide useful benefit to the recipient, the array must be prevented from contacting the rear wall of the cochlea, shown as position B in Figure 3. Therefore, in order to achieve this additional depth without causing damage to the structure of the cochlea, the array is shaped with at least some degree of curvature to extend past the first turn of the cochlea, as shown as C in Figure 3.

Figure 4 shows the device of the present invention that is capable of achieving the required depth of insertion. As shown, the array 30 is of a curved configuration with each of the electrode contacts 32 positioned on the same side of the carrier for stimulation of the desired regions of the cochlea. The array can be inserted into the cochlea in a straight configuration with the use of a straightening stylet inserted into a lumen in the carrier 31, and upon insertion the stylet can be removed allowing the array 30 to assume its natural precurved shape. It is envisaged that the array could also have the electrode contacts 32 positioned on diametrically opposed surfaces of the carrier 31, rather than on the same surface and still fall within the scope of the present invention. It is also envisaged that instead of a straightening stylet being used to maintain the array in a straight position, a bioresorbable stiffening sheath could also be employed to maintain the array in a straight position, with the

sheath being dissolvable upon contact with cochlear fluid or saline solution allowing the array to return to its pre-curved position.

Figure 5 shows a further problem associated with prior art devices 5 postulated to perform the task of the present invention. One of the major problems with prior art devices intended for insertion into the basal section of the cochlea resides in the stability of the electrode. The fixation of the proximal end of the electrode is essential in providing the desired stability of the electrode and to ensure that the electrode will not move or twist and damage 10 the basilar membrane and sensitive structures of the cochlea, thereby affecting the hydrodynamic nature of the cochlea. As is shown in Figure 5, the cochlea is represented diagrammatically as reference numeral 40, with the prior art array being depicted as the shaded region shown by reference numeral 45. During natural body motion, unless the proximal end 42 of the electrode array 15 is properly fixed, an electrode inserted this depth into the electrode will experience a certain degree of rotation or twisting about the axis X-X, causing the electrode to damage the basilar membrane and affect the ability of the cochlea to naturally detect sounds. This is particularly the case where the proximal end of the device is rounded or relies upon flexible flaps or the like to 20 maintain the array in the desired position.

With regard to the electrode array of the present invention as shown in Figure 2a, Figure 2b and Figure 4, the stability of the electrode is ensured through the design of the proximal end of the array. In this design the electrode array is provided with a collar 35 having an abutment surface 37 to stabilise the electrode and reduce any rotation of the device during natural body movement. Further to this, the collar 35 has a mesh portion 36 extending outwardly therefrom that allows the surgeon to anchor the collar to the promontory bone for integration into the fibrous tissue and additional stabilisation. It is considered that the action of this collar provides the desired stability to the device to enable the array to perform its desired function.

The electrode array of the present invention is preferably inserted into the cochlear in the following manner. As the intention of the present invention is to preserve as much of the recipient's residual hearing as possible so that only high frequency sounds are provided electrically, it is desirable that the

structure of the cochlea is left intact as much as possible. Therefore, rather than incising the round window membrane, a cochleostomy is formed. The cochleostomy is preferably made 1mm anteroinferior to the round window and is preferably achieved using either a "soft surgery" technique or by drilling with a laser. The electrode array is then inserted into at least the basal region of the cochlea and secured in place as mentioned above. Prior to closing the cochleostomy, a small amount of facia is placed around the electrode package. In this method the securing in place of the electrode seals the cochleostomy ensuring that the hydrodynamic nature of the cochlea is maintained.

10

The electrode array is preferably made using conventional techniques, from conventional materials, as is known in the cochlear electrode array art. One approach for making a cochlear electrode array according to the present invention is described in International Publication No WO 00/71063, the contents of which are incorporated herein by reference.

Turning to Figure 6, there is shown the device of the present invention according to a second embodiment. In this embodiment, the device is shown generally as 50, and represents the implantable portion of the system. With reference to Figure 1, the receiver coil 23 is shown as well as the receiver stimulator unit 22. Extending from the receiver stimulator unit 22 are three electrode arrays 51, 52, 53. Array 51 corresponds with the short electrode array as described above, which is inserted into the basilar region of the cochlear to provide electrical stimulation for high frequency sounds in accordance with the first embodiment of the present invention. Array 52 is a conventional electrode array consisting of a plurality of electrodes arranged along the length thereof to provide electrical stimulation for sounds of all frequencies as is the case for conventional cochlear implant devices. Array 53 is an extra cochlear electrode as is known in conventional cochlear implants which is positioned remote from the cochlear to provide a reference point for various modes of stimulation.

In this embodiment, a recipient can be implanted with the device 50 and the short array 51 can be inserted into the cochlea of the recipient to provide hearing sensation for sounds having a high frequency. In this case the conventional array 52 can be stored for future use, either by coiling the array in

the mastoid or packaged in a sack, made for example from Teflon, remote from the cochlea. In this regard, should the recipient perceive that middle to low frequency sounds are no longer being experienced through the residual hearing process, then the short array 51 could be simply removed and the conventional array inserted, thereby restoring sound perception for all sound frequencies in the same manner as a conventional cochlear implant device. In this embodiment, the device is easily upgraded to a conventional cochlear implant device should the need arise without the need for extensive explantation and revision surgery.

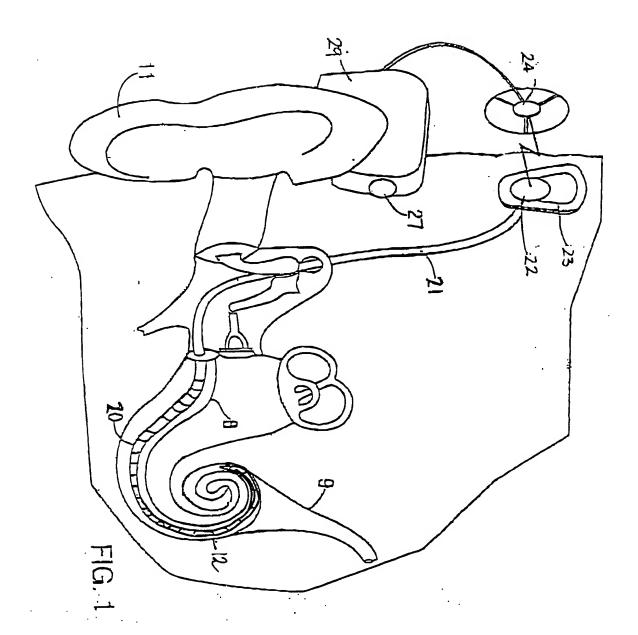
10

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

Dated this twenty eighth day of June 2002

Cochlear Limited
Patent Attorneys for the Applicant:

F B RICE & CO



;)

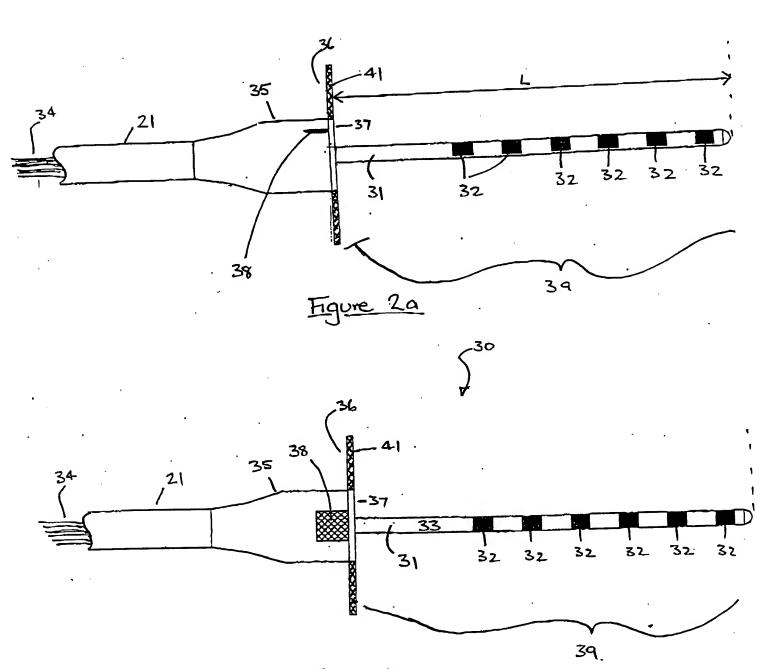


Figure 2b

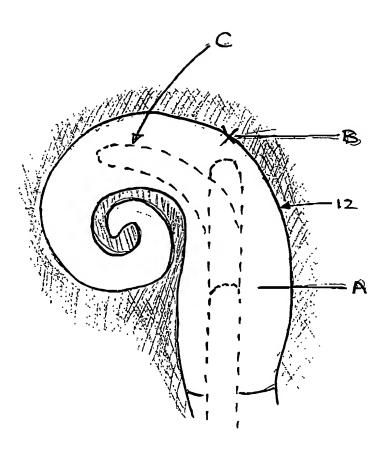
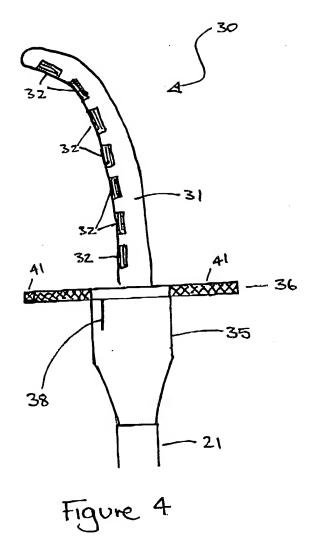


Figure 3



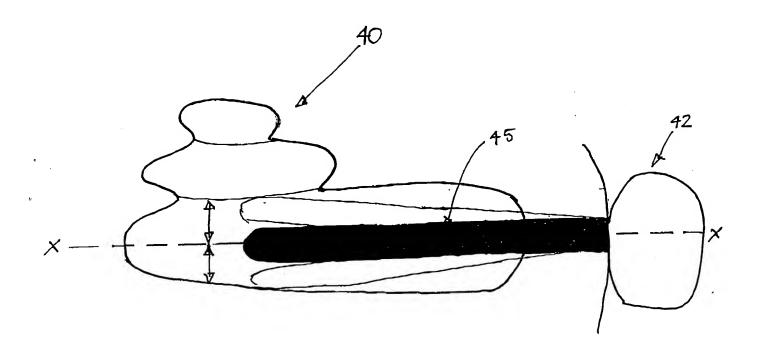
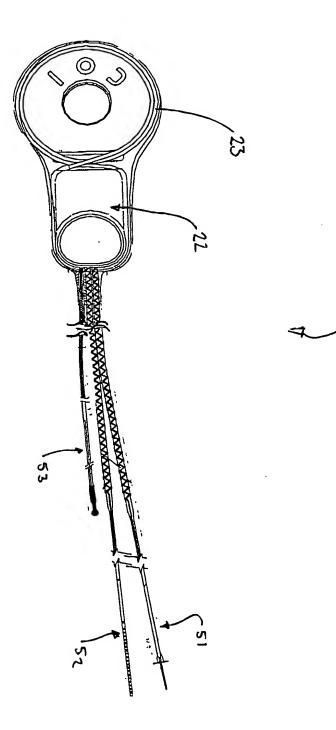


Figure 5

J.J.

(1)



This Page is Inserted by IFW Indexing and Scanning Operations and is not part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

BLACK BORDERS
☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
☐ FADED TEXT OR DRAWING
☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
☐ SKEWED/SLANTED IMAGES
\square COLOR OR BLACK AND WHITE PHOTOGRAPHS
☐ GRAY SCALE DOCUMENTS
☐ LINES OR MARKS ON ORIGINAL DOCUMENT
☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
□ OTHER:

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.